REMARKS

Claims 1-2 and 4-12 are currently pending in this application, with claims 13-24 having been withdrawn from consideration based on an election/restriction requirement, and subsequently canceled. Claim 1 is an independent claim drawn to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric, with claims 2 and 4-7 depending therefrom, while claim 8 is an independent claim also drawn to a composition, with claims 9-12 depending therefrom.

Claims 1-12 stand rejected under 35 USC 112 as being indefinite for lack of recitation of amounts of claimed extracts. Claims 1-7 stand rejected under the judicially created doctrine of double patenting over claim 1 of U.S. Patent No. 6,264,995. Claims 1-7 stand rejected under 35 USC 103(a) as being obvious over Chassagnez-Mendez et al. in view of Woznicki et al. (U.S. Patent No. 4,457,919) and Takagaki (JP4041221164A). Claims 8-12 stand allowed.

The above amendments and following comments are made in anticipation that they will place the application in condition for allowance. With entry thereof, Applicants respectfully submit that the claims are now in condition for allowance.

1. Rejection of Claims 1-7 Under 35 U.S.C. 112

Claims 1-12 (sic) stand rejected under 35 USC 112, second paragraph as being indefinite for failing to distinctly point out and claim the inventive subject matter, for the reasons set forth in the Office Action.

RESPONSE

Applicants have amended claim 1 in accordance with the Examiner's suggestion, and respectfully request reconsideration and withdrawal of the rejection.

Applicants thank the Examiner for his helpful suggestion regarding amending claim 1 to better define the inventive subject matter. Applicants have amended claim 1 by incorporating the limitations of claim 3, thus basically restoring claim 1 to the scope of the originally filed claim. As such, Applicants submit that the amendments to claim 1 are not narrowing, since the claim now recites the subject matter as originally filed in claim 1.

Applicants respectfully submits that the claims are now definite in their scope and respectfully requests reconsideration and withdrawal of this rejection.

2. Rejection of Claims 1-12

under Obviousness-Type Double Patenting

Claims 1-7 stand rejected under the doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,264,995, for the reasons set forth in the office action.

RESPONSE

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting grounds provided the conflicting application or patent is shown to be commonly owned with this application. Accordingly, a terminal disclaimer disclaiming the term of the instant application which would extend beyond the expiration of U.S. Patent No. 6,264,995 is being filed herewith. The filing of the terminal disclaimer, though, is not an admission that the claims of the present application are obvious over U.S. Patent No. 6,264,995, and is not to be construed as such. The terminal disclaimer is being filed only for expediency to overcome the rejection and advance prosecution of this application.

In addition, Applicants are also submitting copies of

assignment documents executed by the inventors in favor of New Chapter Inc. in order to establish New Chapter as the owner of both the present application and the '995 patent. The assignments are being submitted for recordation purposes under separate cover.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-7 under the judicially created doctrine of double patenting.

3. Rejection of Claims 1-7

Under 35 U.S.C. 103(a)

Claims 1-7 stand rejected under 35 U.S.C. 103(a) as being obvious over Chassagnez-Mendez et al. (Brazilian Journal of Chemical Engineering) in view of Woznicki et al. (U.S. Patent No. 4,475,919) and Takagaki (JP4041221164A) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The references of record do not teach or suggest Applicants' inventive subject matter as a whole, as recited in the rejected

claims. Further, there is no teaching or suggestion in these references which would lead the ordinary skilled artisan to modify the references to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial

burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974. Applicants respectfully submit that the Examiner has failed to prove this.

Claim 1 is directed to a composition comprising a supercritical extract and a hydroalcoholic extract of turmeric wherein said composition comprises effective amounts of the supercritical extract and the hydroalcoholic extract of turmeric so as to effect smoke detoxification in a human. Claims 2 and 4-7 depend from claim 1 and necessarily contain all of the limitations found therein.

As an initial matter, Applicants respectfully submit that the recitation of **effective amounts** of the extracts of turmeric provide sufficient structural definition of the composition to remove claim 1 (and the dependent claims) from the purview of the cited prior art references. The claimed composition comprises specific amounts of the supercritical and hydroalcoholic extracts of turmeric. The specific amounts are sufficient to effect smoke detoxification in a human. The specific amounts also provide structural definition to the claimed composition; a structural definition that, Applicants submit, **is not taught, suggested or inherent in any of the cited references nor in any combination of the references.**

Applicants respectfully submit that the Chassagnez-Mendez et al. reference (*A Mass Transfer Model Applied to the Supercritical Extraction...*) teaches supercritical extraction of turmeric for the purpose of food dye. The Chassagnez-Mendez et al. reference teaches a procedure to supercritically extract the curcuminoids from the turmeric plant. However, **the reference is silent as to the inclusion of a hydroalcoholic extract of turmeric along with a supercritical extract in a single composition**. Furthermore, Applicants submit that the Chassagnez-Mendez et al. reference fails to teach that the supercritical extract is present in a composition in a **specific** amount, and in combination with a **specific amount** of a hydroalcoholic extract of turmeric, so as to effect smoke detoxification in a human. As such, Applicants respectfully submit that the Chassagnez-Mendez et al. reference fails to teach all of the limitations of claim 1 (and the claims that depend therefrom).

The Examiner turns to the secondary references in an attempt to cure the deficiencies of the Chassagnez-Mendez et al. reference. In particular, the Examiner cites the Woznicki et al. patent (U.S. Patent No. 4,475,919) and the Takagaki reference (JP4041221164A) as supplying the deficiencies of the Chassagnez-Mendez et al. reference.

Applicant respectfully submits that the Woznicki et al. patent

teaches colored medicinal tablets and natural color pigments and methods for using the natural coloring pigments in coloring food, drug and cosmetic products. The Examiner particularly cites Example II of the Woznicki et al. patent as showing the use of a hydroalcoholic extract of turmeric as such a dye in a particular application. However, Applicants respectfully submit that **the Woznicki patent is silent as to the inclusion of a supercritical extract of turmeric with the hydrocalcoholic extract in a single composition**. Furthermore, Applicants submit that the Woznicki et al. patent fails to teach that the hydroalcoholic extract is in combination with a **specific amount** of a supercritical extract of turmeric, such that the specific amounts of the two extracts effect smoke detoxification in a human. As such, Applicants respectfully submit that the Woznicki et al. patent also fails to teach all of the limitations of claim 1 and the dependent claims.

Furthermore, Applicants respectfully submit that there is **no motivation** to combine the Chassagnez-Mendez et al. reference with the Woznicki et al. patent in an attempt to combine the references. The only discussion in the Woznicki et al. patent of hydroalcoholic extracts of turmeric is in Example II of the specification. The Example discusses the use of the ethanolic extract of turmeric in the preparation of a powdered natural dye pigment. On the other

hand, the Chassagnez-Mendez et al. reference exclusively discusses the preparation of a supercritical extract of turmeric for pigment purposes.

In fact, Applicants respectfully submits that the Chassagnez-Mendez et al. reference **teaches away** from combining it with the Woznicki reference. The Chassagnez-Mendez et al. reference discusses generally, in the introduction, the extraction of oleoresin from turmeric rhizomes through the use of ethanol. However, the reference indicates on page 316 that "in the future the solvent extraction may be avoided as the standard procedure to obtain the curcuminoids since **these pigments are unstable, and hence degrade when submitted to extraction with organic solvents at an elevated temperature.**" (emphasis added). Thus, Applicants submit that one of ordinary skill in the art clearly would **not** be led by the teachings of the Chassagnez-Mendez et al. reference to combine a hydroalcoholic extract of turmeric with a supercritical extract of turmeric, and instead would be led to avoid including hydroalcoholic extracts of turmeric since the hydroalcoholic extracts **are unstable** in those applications. Further, there is no teaching the Woznicki et al. patent to combine the hydroalcoholic extract prepared therein with a supercritical extract of turmeric. Thus, Applicants respectfully submit that there is no motivation or

teaching to combine the Chassagnez-Mendez et al. reference with the Woznicki et al. patent in an attempt to achieve the presently claimed invention, and that the Chassagnez-Mendez et al. patent teaches away from such combination.

In addition, assuming *arguendo* that the references were combined in an attempt to achieve the presently claimed invention, Applicants respectfully submit that such a combination still would not achieve the claimed invention. In particular, since neither the Chassagnez-Mendez et al. reference nor the Woznicki et al. patent teach the specific effective amounts of the supercritical and hydroalcoholic extracts of turmeric, **the resultant products of a combination of the references would also not teach the specific effective amounts as claimed in claim 1 and the dependent claims.** Thus, Applicants submit that the Examiner has failed to show that the combination of references teaches each of the claimed limitations, as well as failing to point out the motivation for combining the references in an attempt to achieve the presently claimed invention.

The Examiner relies on the Takagaki reference to provide teaching of an aqueous extract of green tea (claim 5). The abstract and purpose of the Takagaki reference describes using the aqueous extract of green tea to stabilize the color and tone of

carotenoid-containing food. However, Applicant respectfully submits that the Takagaki reference fails to teach or disclose the presence of a supercritical extract of turmeric and a hydroalcoholic extract of turmeric present in specific amounts effective for smoke detoxification in a human. The green tea in the Takagaki reference is used as a preservative and stabilizer for food colors, and has nothing to do with smoke detoxification.

Since the Takagaki reference fails to cure the deficiencies of the Chassangez-Mendez et al. reference and the Woznicki et al. patent, if the Takagaki reference was combined with the other two references, Applicants submit that the combination of the references still would not achieve the presently claimed invention. Particularly, even if all three references were combined in an attempt to achieve the presently claimed invention, **the resultant products of a combination of the references would also not teach the specific effective amounts of the supercritical and hydroalcoholic extracts of turmeric, as claimed in claim 1 and the dependent claims** (including claim 5). All three references are silent as to these limitations, especially considering that none of the references are directed to smoke detoxification in humans. Thus, the combination of all three references would not achieve the presently claimed invention.

Additionally, Applicants respectfully submit that the cited

references are from a **nonanalogous art**, and thus one of ordinary skill in the art of treating by smoke detoxification **would not** look to food dyes and pigments for a combination of supercritical and hydrocalcoholic extracts of turmeric. Each of the cited references are directed toward the use of turmeric extracts and green tea extracts as dyes, pigments and stabilizers in foodstuffs. Thus, the cited prior art is directed to the food industry. The presently claimed invention, on the other hand, is directed to the composition and use thereof involving smoke detoxification in a human. The presently claimed compositions contain amounts of the components that effect detoxification of smoke in a human. Thus, the composition is for a biological purpose, whereas the separate components listed in the cited references are used in food items, not for the treatment of humans. Accordingly, Applicants submit that the cited references are nonanalogous art with respect to the presently claimed invention, and one of ordinary skill in the art of smoke detoxification **would not** look to the references in an attempt to achieve the presently claimed invention.

Applicants have shown that a combination of the Chassagnez-Mendez et al. reference, the Woznicki et al. patent and the Takagaki reference fails to teach all of the claimed limitations, and there is no motivation to modify the references in an attempt to do so. Thus, Applicants submit that the Examiner has failed to

prove a prima facie case of obviousness with respect to claims 1-7.

Accordingly, Applicants respectfully submit that the claims are unobvious over the combination of references, and respectfully request reconsideration and withdrawal of this rejection.

4. Allowable Subject Matter

The Examiner has indicated that claims 8-12 are allowed. Applicants acknowledge this indication and are grateful therefor.

CONCLUSION

In view of the foregoing, applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,
NATH & ASSOCIATES PLLC

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